

WOODROW WILSON REHABILITATION CENTER POLICIES AND PROCEDURES	
Title: RESEARCH POLICY	
Policy Number: 1.25	
Effective Date: January 1, 2008	Page 1 of 5
Lead Department: Organizational Development and Quality Assurance	

OBJECTIVES

- (1) To demonstrate organizational leadership for strategic pursuit and management of innovative rehabilitative research initiatives, reflective of WWRC's vision, mission, values, and Center of Excellence priorities.
- (2) To ensure that WWRC rehabilitative research initiatives are planned and conducted in full compliance with federal and State laws and DRS regulations, policies and procedures governing human subject research.
- (3) To ensure that WWRC researchers and other staff involved in human subjects research have the training needed to appropriately conduct their research activities.

DEFINITIONS

- *Research* means the systematic investigation, experiment, study, evaluation, demonstration or survey, designed to develop or contribute to general knowledge (*basic research*) or specific knowledge (*applied research*). Activities which meet this definition constitute research for purposes of this policy, whether or not they are supported or funded under a program which is considered research for other purposes {22VAC 30-40-10}. For example, some grants and/or demonstration and service programs may include research activities.
- *Human Subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or identifiable private information.
- *Human Subject Research* means a systematic investigation, experiment, study, evaluation, demonstration, or survey designed to develop or contribute to general knowledge (*basic research*) or specific knowledge (*applied research*) in which a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or through review of identifiable private information {22VAC 30-40-10}. Quality assurance/improvement activities may also be research activities and must be evaluated on a case-by-case basis to determine whether the planned activities meet the definition of research.
- *Non-therapeutic research* means human research in which there is no reasonable expectation of direct benefit to the physical or mental condition of the participant (Section 32.1-162.16, Code of Virginia).
- *Human Subject Research Compensation* is "payment" to research participants when approved by the HRRC for such things as time, discomfort, and inconvenience directly resulting from participation in a research activity.
- *Human Subject Research Reimbursement* is funds paid to a research participant for travel expenses incurred as a direct result of participating in the research, such as mileage, lodging, and food.

POLICY

To build capacity towards its vision as a “community of service excellence in medical and vocational rehabilitation for people with disabilities”, WWRC shall collaborate with targeted universities and state/national organizations and entities in human subject research regarding vocational and medical rehabilitation, within available resources and defined organizational priorities. This commitment to shared rehabilitation research is demonstrated through:

- Defined Strategic Plan goals and objectives and Center of Excellence research priorities, consistent with WWRC’s mission, vision, and values;
- Targeted development and nurturing of partnerships with targeted universities and state/national organizations and entities for rehabilitation research initiatives and grant funding, as appropriate;
- Centralized coordination of research initiatives through the WWRC Organizational Development and Quality Assurance Division to provide policy guidance, technical assistance and consultation, directly and/or through resource coordination with extended team members within the Agency;
- Standardized protocols for development and submission of rehabilitative research proposals; and,
- Facilitated access to targeted education, training, and professional development opportunities designed to increase knowledge, skills, and abilities of WWRC employees interested in rehabilitative research.

Any human subject research conducted at WWRC, or involving WWRC clients or staff, shall comply with DRS Policies and Procedures for the Protection of Human Subjects Involved in Research (<http://www.vadrs.org/hrrc>), human subjects laws and regulations, and the procedures contained in this policy. WWRC shall not engage in any human subject research which poses more than minimal risk to the human subject. WWRC shall not engage in any non-therapeutic research unless it is determined by the DRS HRRC that such non-therapeutic research will not present greater than minimal risk to the human subject. Human subject compensation and/or reimbursement for participation in research shall not be offered to a human subject as a means of coercive persuasion or without contingent on the human subject’s participation in the research.

WRITTEN PLAN FOR COLLABORATIVE REHABILITATION RESEARCH INITIATIVES

Through core and extended team processes, the WWRC Organizational Development and Quality Assurance (OD&QA) Division is accountable for pursuit and management of innovative rehabilitation research opportunities that are aligned with and supportive of the WWRC Strategic Plan and Center of Excellence priorities, as documented in the annual *Blueprint for Direction*. The OD&QA Division is also responsible for centralized coordination, tracking, and monitoring of rehabilitation research initiatives, in accordance with established DRS policies and procedures. Core and extended Agency OD&QA team members are available as consultants to provide assistance for program staff who may be interested in rehabilitation research opportunities and/or who are research grant recipients. Protocols for participation in rehabilitation research follow.

Step #1: Preliminary Administrative Approval

A request for WWRC participation in rehabilitation research may be initiated by a WWRC employee or group of employees, or by a university or other organization/entity. All requests must be made or referred to the Director, WWRC OD&QA Division (or designee).

The OD&QA Division Director (or designee) will compile and provide information about the request to the appropriate WWRC Division Director and WWRC Director to seek preliminary administrative approval of the request. The WWRC Division Director and appropriate Division Director will determine whether preliminary administrative approval will be provided, based on factors such as:

- Anticipated Advancement of Knowledge in the Field
- Alignment with WWRC Vision, Mission, and Values
- Alignment with WWRC Strategic Plan and annual *Blueprint for Direction* priorities
- Anticipated Fiscal and Program Impact
- Feasibility of Resource Commitment

The WWRC Division Director will notify the OD&QA Division Director (or designee), in writing, of the preliminary administrative decision for the research request. If approved, the proposal development process proceeds to step #2. If denied, the reason will be provided and the OD&QA Division Director (or designee) will notify the requesting party.

Response Timeframe: 1-3 business days from receipt of request

Step #2: Determining Feasibility and Organizational Benefit through Administrative Committee Review

Upon receipt of preliminary administrative approval, the WWRC OD&QA Division Director (or designee) will meet with the requesting party/researcher(s), his/her supervisor, and members of a defined Administrative Review Committee, the membership of which will be determined by the nature of the proposed research. The purpose of the Administrative Review Committee is to discuss technical aspects of the proposed rehabilitation research and to determine if the proposed research is both feasible and cost-beneficial to pursue from an organizational perspective.

Questions to be considered include:

- Cost/Benefit Analysis - What WWRC resources will be utilized (fiscal, facilities, clients, personnel)? How much will the research cost over time? Are there “hidden costs”? How does the anticipated cost “fit” with proposed impact and value for WWRC?
- Safety/Liability Issues – Does the proposed research meet the definition of minimal risk (22 VAC 30-40-10)? Are there other liabilities to be considered from an organizational perspective (facilities, equipment, etc.)?
- Subject Availability - Will there be enough subjects available who meet criteria and are willing to participate? Will the proposed number result in enough data from which to draw statistically significant conclusions? Methodology - Is it well thought-out? Does there appear to be a strong hypothesis and relevant statistical process? Will there be controls? Literature Reviews - will this research contribute to already available general knowledge or “break ground” with innovative concepts?
- Personnel - Who and what are credentials of the proposed researchers? How will researchers interact with other WWRC staff? Have proposed researchers completed the required Investigator 101 training and is there written verification that this is current for the proposed research period?

A summary of this meeting, with the recommendations and decisions, will be documented and maintained on file in OD&QA. The Administrative Review Committee may decide to allow the proposal to proceed to step #3, postpone the decision pending further information, or notify the WWRC Director and Division Director that the proposal is denied, with reasons provided.

Response Timeframe: Within 2 weeks

Step #3: Developing and Refining the HRRC Application Through Peer Review

The requesting Researcher(s) will meet with a Peer Review Committee, the membership of which will be determined by the nature of the proposed research. The purpose of the Peer Review Committee is to offer expert consultation and critique of the proposal, anticipated to result in a complete HRRC Application. The literature review findings, hypothesis, methodology, and statistical processes will be discussed in detail as will be issues of Human Protection, confidentiality and consent.

Response Timeframe: A set of written recommendations to guide the Researcher(s) in completion of the HRRC Application will be provided within 5 business days following the Peer Review Committee discussion.

Step #4: Developing and Submitting the Formal HRRC Application

The completed HRRC Application must be submitted to the OD&QA Division Director for review prior to submission to the HRRC. The OD&QA Administration Office will track and monitor the application from submission to approval.

Response Timeframe: The application package will be submitted to the DRS HRRC within 2-3 business days of receipt in OD&QA.

Step #5: Agency HRRC Response

Within 45 days of receiving a complete application, the Agency HRRC must complete its review, in accordance with established HRRC Policies and Procedures for the Protection of Human Subjects Involved in Research (<http://www.vadrs.org/hrrc/downloads/ProceduresManual.doc>). All communication will be sent directly to the designated Project Investigator, with copies to the appropriate WWRC Program Manager/Supervisor and the OD&QA Division Office.

ANNUAL CERTIFICATION

No later than 45 days after the end of the state fiscal year, WWRC shall send a written report to the DRS Commissioner giving assurance that all human subjects research conducted during the fiscal year was reviewed and approved by the DRS HRRC prior to implementation of that research or that no human subjects research was conducted during that fiscal year. This certification shall be developed by the Division Director, OD&QA, and signed by the WWRC Director.

TRAINING

The WWRC Division Director, OD&QA, shall ensure that WWRC researchers and other staff involved in human subjects research have the training needed to appropriately conduct their research activities. The OD&QA Division Director shall also ensure that any needed training funds to support WWRC employees in developing research skills are included in the Annual WWRC Staff Training and Development budget. Training will be coordinated with the DRS HRRC, where feasible and appropriate.

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Reviewed 12/03